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EXAMINER

MOHANDESI, JILA M

ART UNIT PAPER NUMBER

3728

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,235

Applicant(s)

CLOUGH, JAMES G.

Examiner

Jila M Mohandesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2004 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. application 10/032,604, which has been allowed and pending publication. Although the conflicting claims are not identical, they are not patentably distinct from each other because application 10/032,604 claims a more specific embodiment than the instant application.

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Once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention, because the more specific "anticipates" the broader. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1, 10 and 18, the phrase "in proximal to distal direction" is vague and indefinite. It is not clear which proximal to distal direction the claim refers to.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1- 3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothbart (6,092,314). Rothbart '314 discloses an orthopedic appliance, comprising a

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wedge (60) for placement under the phalanges of a toe forward of the center of a first metatarsal, (The wedge is clearly forward the center of a first metatarsal, as shown in Figure 6 embodiment), the wedge having a top surface adapted to support the toe and a lower surface, wherein an angle of inclination between the top surface and the bottom surface is between 1 and 60 degrees. See Figures 7A-7D embodiments.

All the functional claim language and statements of intended use do not make an otherwise unpatentable claim patentable. It is believed to be well settled that "recitation with respect to manner in which claimed apparatus is intended to be employed does not differentiate claimed apparatus from prior art apparatus satisfying structural limitations of that claimed, "*Ex parte Masham* 2 USPQ2nd 1674. Also *Ex parte Casey* 152 USPQ 235. The law of anticipation does not require that an anticipatory reference teach what the applicant is claiming or has disclosed, but only that the claims "read on" something disclosed in the reference, i.e., all limitations of the claim are found in the reference. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 871 (Fed Cir. 1983). Furthermore, it is only necessary that the reference include structure capable of performing the recited function in order to meet the functional limitations of a claim. See *In re Mott*, 557 F.2d 266, 194 USPQ 305 (CCPA 1977). Since the reference device has all of the same structural elements, as noted above, it would clearly seem to be inherently capable of performing the functions as claimed.

With respect to claim 3 and the support being formed integrally, see column 7, lines 45-48.

With respect to claim 6 and the concave depression, see Figure 8 embodiment and column 7, lines 1-3.

Since applicant has not identified the proximal phalanx to be the **first** proximal phalanx of the toe that is deflected between 1 and 60 degrees upwardly in a **first** proximal **phalanx** to a **first** distal **phalanx** direction, relative to the first metatarsal, any of the second, third and forth proximal phalanx that are deflected with respect to the first metatarsal in Rothbart '314 will read on the claims as presented.

8. Claims 1, 5 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tager (4,333,472). Tager '472 discloses an orthopedic appliance, comprising a wedge (resilient foam 10) for placement under the phalanges of a toe forward of the center of a first metatarsal (see Figure 9 embodiment which clearly shows the wedge not extending under the center of a first metatarsal), the wedge having a top surface adapted to support the toe and a lower surface, wherein an angle of inclination between the top surface and the bottom surface is between 1 and 60 degrees (see column3, line 9).

All the functional claim language and statements of intended use do not make an otherwise unpatentable claim patentable. It is believed to be well settled that "recitation with respect to manner in which claimed apparatus is intended to be employed does not differentiate claimed apparatus from prior art apparatus satisfying structural limitations of that claimed, "*Ex parte Masham* 2 USPQ2nd 1674. Also *Ex parte Casey* 152 USPQ 235. The law of anticipation does not require that an anticipatory reference teach what the applicant is claiming or has disclosed, but only that the claims "read on" something

disclosed in the reference, i.e., all limitations of the claim are found in the reference. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 871 (Fed Cir. 1983). Furthermore, it is only necessary that the reference include structure capable of performing the recited function in order to meet the functional limitations of a claim. See *In re Mott*, 557 F.2d 266, 194 USPQ 305 (CCPA 1977). Since the reference device has all of the same structural elements, as noted above, it would clearly seem to be inherently capable of performing the functions as claimed.

Since applicant has not identified the proximal phalanx to be the **first** proximal phalanx of the toe that is deflected between 1 and 60 degrees upwardly in a **first** proximal **phalanx** to a **first** distal **phalanx** direction, relative to the first metatarsal, any of the second, third and forth proximal phalanx that are deflected with respect to the first metatarsal in Tager `472 will read on the claims as presented.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being obvious over Rothbart `314. With respect to claims 4 and 5 which further limits the material of the orthopedic appliance, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the orthopedic appliance from different material, since it has been held to be within the general skill of a worker in the art to select a

known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

11. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothbart '314 in view of either Brock '927 or Jacoby '046. Rothbart '314 as described above discloses all the limitations of the claims except for the orthopedic appliance having a fastener. Each of Brock '927 and Jacoby '046 disclose fastening an orthopedic appliance to the toe of a wearer to better secure and hold the appliance to the toe of the wearer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide fastener to the orthopedic appliance of Rothbart '314, as taught by each of Brock '927 and Jacoby '314 to better secure and hold the orthopedic appliance to the toe of the wearer.

12. Claims 7-9 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tager '472 in view of either Brock '927 or Jacoby '046. Rothbart '314 as described above discloses all the limitations of the claims except for the orthopedic appliance having a fastener. Each of Brock '927 and Jacoby '046 disclose fastening an orthopedic appliance to the toe of a wearer to better secure and hold the appliance to the toe of the wearer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide fastener to the orthopedic appliance of Tager '472, as taught by each of Brock '927 and Jacoby '314 to better secure and hold the orthopedic appliance to the toe of the wearer.

13. Claims 18-23 are directed to the obvious method of using the orthopedic appliance of Tager '472. Tager '472 discloses providing a wedge (10) having a top

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surface positioned substantially under the phalanges of a toe and a bottom surface; and elevating the toe to a predetermined angle of inclination using the wedge. Tager '472 as modified above discloses fixing the wedge to the toe using a fastener.

With respect to claim 21, Tiger '472 discloses fixing the bottom surface of the wedge to a piece of footwear (see column 3, lines 22-25).

14. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothbart '314 in view of Tager '472. Rothbart '314 as described above discloses all the limitations of the claims except for the orthopedic appliance comprising a top surface adapted to support the phalanges of a toe and not extending under the center of a first metatarsal. Tager '472 discloses an orthopedic appliance, comprising a wedge for placement under the phalanges of a toe forward of the center of a first metatarsal and not extending under the center of a first metatarsal to reduce or eliminate the manifest symptoms resulting from a specific structural abnormality. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the orthopedic appliance of Rothbart '314 not extend under the center of the first metatarsal as taught by Tager '472 to reduce or eliminate the manifest symptoms resulting from a specific structural abnormality.

With respect to claim 13 and the support being formed integrally, see column 7, lines 45-48.

With respect to claim 14 and the concave depression, see Figure 8 embodiment and column 7, lines 1-3.

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15. Claims 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above references as applied to claim 10 and further in view of either Brock '927 or Jacoby '046. Rothbart '314 as modified above discloses all the limitations of the claims except for the orthopedic appliance having a fastener. Each of Brock '927 and Jacoby '046 disclose fastening an orthopedic appliance to the toe of a wearer to better secure and hold the appliance to the toe of the wearer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide fastener to the modified orthopedic appliance of Rothbart '314, as taught by each of Brock '927 and Jacoby '314 to better secure and hold the orthopedic appliance to the toe of the wearer.

Claims 18-23 are directed to the obvious method of using the orthopedic appliance of Rothbart '314. Rothbart '314 discloses providing a wedge (10) having a top surface positioned substantially under the phalanges of a toe and a bottom surface; and elevating the toe to a predetermined angle of inclination using the wedge. Rothbart '314 as modified above discloses fixing the wedge to the toe using a fastener.

Response to Arguments

Applicant's arguments filed March 08, 2004 have been fully considered but they are not persuasive. Since applicant has not identified the proximal phalanx to be the **first** proximal phalanx of the toe that is deflected between 1 and 60 degrees upwardly in a **first** proximal **phalanx** to a **first** distal **phalanx** direction, relative to the first metatarsal, any of the second, third and forth proximal phalanx that are deflected with respect to the

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first metatarsal in both Rothbart '314 and Tager '472 will read on the claims as presented.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M Mohandesi whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

**JILA M. MOHANDESI
PRIMARY EXAMINER**



Jila M Mohandesi
Primary Examiner
Art Unit 3728

JMM
January 12, 2005